Indiana State Department of Health
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Mitchell E. Daniels, Jr.
Governor

Judith A. Monroe, M.D.
State Health Commissioner

DATE: October 27, 2009

TO: All Local Health Departments
Attn: Chief Food Inspection Officer

FROM: A. Scott Gilliam, MBA, CP-FS ASG
Manager, Food Protection Program

SUBJECT: Qualitest Pharmaceuticals Recall

SUGGESTED ACTION: **Unclassified Recall; Accusure® Insulin Syringes; Recommend notification of affected stores via phone, fax or e-mail.**

From the information provided by FDA, the product being recalled was distributed in the State of Indiana. These syringes were distributed between January 2002 and October 2009 to wholesale and retail pharmacies nationwide (including Puerto Rico). Detail information is not available at this time. In addition, if any recalled product is found, please notify this office at 317-233-7360.

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Recall -- Firm Press Release

FDA posts press releases and other notices of recalls and market withdrawals from the firms involved as a service to consumers, the media, and other interested parties. FDA does not endorse either the product or the company.

Qualitest Pharmaceuticals Issues a Voluntary Nationwide Recall of All Accusure® Insulin Syringes

Contact:
Larry Kass,
1-800-444-4011

FOR IMMEDIATE RELEASE - October 27, 2009 - Huntsville AL-Qualitest Pharmaceuticals today issued a voluntary nationwide recall of all Accusure® Insulin Syringes. The distributed syringes are of the following descriptions and NDC numbers: 28G 1/2cc, NDC 0603-6995-21;28G 1cc, NDC 0603-6996-21; 29G 1/2cc NDC 0603-6997-21, 29G 1cc, NDC 0603-6998-21, 30G 1/2cc, NDC 0603-999-21, 30G 1cc, NDC 0603-7000-21, 31G 1/2cc, NDC 0603-7001-21; and 31G 1cc, NDC 0603-7002-21. All Accusure® Insulin Syringes regardless of lot number are subject to this recall. These syringes were distributed between January 2002 and October 2009 to wholesale and retail pharmacies nationwide (including Puerto Rico). The syringes in these lots may have needles which detach from the syringe.

If the needle becomes detached from the syringe during use, it can become stuck in the insulin vial, push back into to the syringe, or remain in the skin after injection.

Consumers who have any Accusure® Insulin Syringes should stop using them and contact Qualitest at 1-800-444-4011 for reimbursement. You can find the lot number on the white paper backing of each individual syringe.

Qualitest is notifying all customers who received these syringes and arranging for the return of any affected product.

The recall is being made with the knowledge of the Food and Drug Administration.

Consumers with questions may contact Qualitest at 1-800-444-4011 for more information.

Adverse reactions or quality problems experienced with the use of this product may be reported to FDA's MedWatch Adverse Event Reporting program either on line, by regular mail or by fax.

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  - Online:www.fda.gov/medwatch/report.htm
  - Regular Mail: Use postage-paid FDA form 3500 available at: www.fda.gov/medwatch/getforms.htm
    Mail to MedWatch 5600 Fishers Lane, Rockville, MD 20852-9787
  - Fax: 1-800-FDA-0178

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